

provide all available expertise and information to date giving the company full access to existing data and data developed pursuant to the CRADA.

The successful company will provide the necessary scientific, financial and organizational support to characterize and test the animals.

Background information is available from the above-referenced address. Patent applications and pertinent information not yet publicly described can be obtained under a Confidential Disclosure Agreement.

The CRADA aims include the rapid publication of research results and the timely exploitation of commercial opportunities. The CRADA partner will enjoy rights of first negotiation for licensing Government rights to any inventions arising within the scope of the agreement. The license option and commercialization of inventions shall not conflict with NIH Guidelines for the availability of transgenic/knockout animals (<http://www1.od.nih.gov/wals/transgen.html>).

The expected duration of the CRADA will be 2 years.

The role of the Laboratory of Metabolism in this CRADA will be as follows:

1. Isolate and characterize genomic clones of human CYP2D6 and CYP3A4.
2. Generate mice by standard injections of oocyte pronuclei and screen founders.

3. Characterize tissue specificity of expression.

4. Jointly publish research results.

The role of the Collaborator will be:

1. Characterize in vitro metabolism using hepatic microsomal fractions.

2. Evaluate in vivo pharmacokinetics with probe substrates and proprietary compounds.

3. Analyze the role of CYP2D6 and CYP3A4 on bioavailability and efficacy of test compounds.

4. Jointly publish research results.

Selection criteria for choosing the CRADA partner will include but not be limited to:

1. Ability to collaborate with NCI on further research and development of this technology. Demonstration of experience and expertise in this or related areas of technology and the ability to provide intellectual contribution to the ongoing research and development. Ability to accomplish objectives according to an appropriate timetable to be outlined in the Collaborator's proposal.

2. Willingness to comply with NIH IRP Guidelines for the Availability of Transgenic/Knockout Animals (<http://www1.od.nih.gov/wals/transgen.html>). The proposal should specifically

address the methods by which the animals will be made available.

3. Demonstration of the resources (facilities, personnel and expertise) necessary to perform research, development and commercialization of this technology.

4. Commitment of reasonable effort and resources on research, development and commercialization of this technology.

5. Expertise in the commercial development, production, marketing and sales of products related to this area of technology.

6. The level of financial support the Collaborator will supply for CRADA-related Government activities.

7. A willingness to cooperate with the National Cancer Institute in the publication of research results.

8. An agreement to be bound by the DHHS rules involving human subjects, patent rights and ethical treatment of animals.

9. A willingness to accept the legal provisions and language of the NIH model CRADA with modifications to address selection criteria #2 and other minor modifications.

10. Provisions for distribution of patent rights to any inventions. Generally, the rights of ownership are retained by the organization which is the employer of the inventor, with (1) an irrevocable, nonexclusive, royalty-free license to the Government (when a company employee is the sole inventor) or (2) an option to negotiate an exclusive or nonexclusive license to the company on terms that are appropriate (when the Government employee is the sole inventor).

Dated: November 21, 1997.

**Kathleen Sybert,**

*Acting Director, Technology Development and Commercialization Branch, National Cancer Institute, NIH.*

[FR Doc. 97-31638 Filed 12-2-97; 8:45 am]

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following National Cancer Institute Special Emphasis Panel (SEP) meeting:

*Name of SEP:* Cancer Genetics Network—Informatics and Information Technology Group.

*Date:* December 9–10, 1997.

*Time:* December 9–7:30 p.m. to Recess. December 10—8:00 a.m. to Adjournment.

*Place:* Ramada Inn—Rockville, 1775 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Gerald Lovinger, Ph.D., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 630C, 6130 Executive Boulevard, MSC 7405, Bethesda, MD 20892-7405, Telephone: 301/496-7987.

*Purpose/Agenda:* To review, discuss and evaluate grant applications.

This notice is being published less than 15 days prior to the meeting due to the urgent need to meet timing limitations imposed by the review and funding cycle.

The meeting will be closed in accordance with the provisions set forth in secs. 552b(c)(4) and 552b(c)(6), Title 5, U.S.C. Applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

(Catalog of Federal Domestic Assistance Program Numbers: 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control)

Dated: November 25, 1997.

**LaVerne Y. Stringfield,**

*Committee Management Officer, NIH.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; Notice of Closed Meeting

Pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting of the National Cancer Institute Special Emphasis Panel (SEP):

*Name of SEP:* Informatics Support for Breast and Colon Cancer Cooperative Family Registries.

*Date:* December 8, 1997.

*Time:* 9:00 a.m. to Adjournment.

*Place:* Executive Plaza North, Conference Room C, 6130 Executive Boulevard, Bethesda, MD 20892.

*Contact Person:* Courtney M. Kerwin, Ph.D., M.P.H., Scientific Review Administrator, National Cancer Institute, NIH, Executive Plaza North, Room 630I, 6130